Docket No. 101896-706 (DEP5128USNP)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
John A. Sazy	
Application No. 10/655,571	Conf. No. 6429
Filed: September 4, 2003	Art Unit: 3738
For: INTERVERTEBRAL CAGE AND METHOD OF USE	Examiner: Brian E. Pellegrino

Boston, Massachusetts
June 6, 2008

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is DePuy Spine, Inc., a Johnson & Johnson company. DePuy Spine, Inc. of Raynham, Massachusetts derives its rights in this application by virtue of an assignment of the application from John A. Sazy to DePuy AcroMed, Inc. as recorded at Reel 014417, Frame 0938, and a change of name from DePuy AcroMed, Inc. to DePuy Spine, Inc., of Raynham, Massachusetts as recorded at Reel 014760, Frame 0975.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1, 3, 5, 6 and 10-31 are currently pending in the present application. According to the Final Office Action mailed on November 20, 2007 and the Advisory Action mailed April 2, 2008, each of claims 1, 3, 5, 6 and 10-31 stand finally rejected. Accordingly, claims 1, 3, 5, 6 and 10-31 are subject to this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention claimed in the pending application generally relates to an intervertebral prosthesis for implantation between adjacent vertebrae of the human spine. In particular, the present invention provides an implant that can be safely inserted in a variety of implantation procedures. To fully understand the claimed invention, it is first necessary to appreciate the state-of-the-art at the time of Appellant's invention, which represents the background against which the claimed invention was developed.

A. The Problem Addressed by the Invention Is the Cumbersome and Sometimes Hazardous Manipulation and Insertion of a Spinal Implant

Genetic or developmental irregularities, trauma, chronic stress, tumors, and degenerative wear are typical causes which can result in spinal pathologies for which surgical intervention is necessary. Where a failure of the intervertebral disc is concerned, the inter-body fusion implant is often chosen. An inter-body fusion maintains disc height, helps to protect the nerve root and restores weight-bearing ability to anterior structures. [¶¶ 0006-7.]

Procedures for implanting spinal inter-body fusion prostheses can be challenging. Anterior approaches and fusion in the cervical spine have gained wide acceptance by both neurosurgeons and orthopedic surgeons as treatment for herniated discs, trauma and related degenerative conditions. In the case of lower lumbar spine problems, such techniques have had more sporadic success. Pedicle screws and rods have allowed surgeons to reduce degenerative conditions and immobilize the motion segment, but have not eliminated the need for weight-bearing support for the anterior spinal column. [¶ 0007.]

The prior art implant techniques for addressing these issues have generally involved implanting two smaller component implant assemblies. While addressing some concerns, the surgical procedures for installing these devices can be complicated and traumatic to the patient. Although X-ray imaging can be used to determine the approximate location of the respective two component assemblies, alignment of the two component prostheses can be of major concern. [¶ 0008.]

B. The Invention Solves the Problem by Providing an Implantation Device to Facilitate the Easy, Safe, and Efficient Insertion of a Spinal Implant

Accordingly, it is an object of the present invention to provide a new and improved single component inter-body fusion cage which overcomes known deficiencies of the prior art while providing improved overall results. [¶ 0009.]

The shape of the claimed prosthesis, in particular "a unitary body that is banana-shaped as viewed from above," is critical to Applicant's invention. This feature has been included in each claim and is highlighted in the specification. For example, the specification provides:

> FIG. 6 shows the banana-shaped cage of the invention 15 within the disc space, as view[ed] from above. Note that the cage 15 is curved so that it mirrors the natural radius of curvature of the anterior and posterior curves of the vertebral bodies. [¶ 0042.]

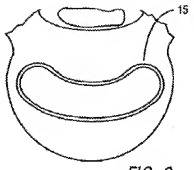


FIG. 6

> The unitary cage 15 can be placed from an anterior position (anterior interbody fusion or ALIF), or posteriorly (posterior lumbar interbody fusion or PLIF, tranforaminal interbody fusion or TLIF). The cage is curved so that it mirrors the natural radius or curvature of the anterior and posterior curves of the vertebral bodies. It can be placed from an anterior position or posterolateral position after standard discectomy. [¶ 0041.]
>
> * * *
>
> FIG. 2 shows the implant device of the invention, designated generally as 15. In the preferred embodiment illustrated, the unitary body 15 is a cage configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure. [¶ 0038.]

Further, Applicant has explicitly described the advantages of the claimed prosthesis have the recited shape relative to prior art systems. Specifically, as stated at paragraph 0050:

> An invention has been provided with several advantages. The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use.

Applicant has thus provided a uniquely-shaped prosthesis that has solved a number of issues relating to its safe implantation.

C. The Single Independent Claim at Issue

There is only one independent claim pending in this application: claim 1. Claim 1 recites an intevertebral prosthesis for implantation between adjacent vertebrae of the human spine (13). As such, the prosthesis includes a unitary body (15) configured and sized to be inserted between

adjacent vertebrae in a single step implantation procedure. [¶0010.] Importantly, the unitary body (15) is banana shaped when viewed from above. The unitary body (15) includes interior (19) and exterior (17) surfaces, and the interior surface (19) defines an interior recess. The unitary body (15) also defines openings (21) that are evenly spaced about a circumference of the unitary body. Finally, the banana shape of the unitary body includes a front arc that has a first radius of curvature (R_1) and a back arc that includes a second radius of curvature (R_2).

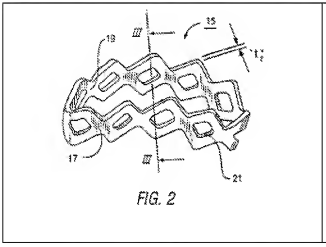


FIG. 2

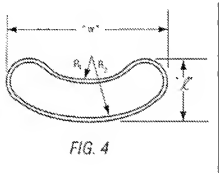


FIG. 4

D. Key Dependent Claims

In order to make even more clear how it is that the banana-shape that provides these many advantages is different from the prior art, Applicant has further defined the banana-shape by characterizing the radii (R_1 and R_2) of the banana-shaped prosthesis (15) (claims 3, 5 and 6), specifying the length (l) and width (w) of the banana-shaped prosthesis (claims 24, 25 and 31), and, most importantly, by ***specifying the ratio of width to length of the banana-shaped prosthesis (claim 30 and claim 25***, which recites the ranges of width and length for the banana-shaped prosthesis that fall within the ratio of claim 30). Each of these claimed elements is important in defining the shape of the prosthesis, but ***it is the ratio of width to length that most clearly differentiates the banana-shape of the present invention from the kidney-shapes of the prior art***, allowing the prosthesis to provide proper support for the spinal column while being insertable from various directions and avoiding the pitfalls of the prior art.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Rejection under 35 U.S.C. 102 of Claims 1, 3, 5, 6, 13, 14, 19, 28 and 30

In the final office action, the Examiner has rejected claims 1, 3, 5, 6, 13, 14, 19, 28 and 30 under 35 USC 102(e) as being anticipated by Schafer (US 6,143,032). Specifically, the Examiner states:

> Fig. 3 shows a unitary body that is banana-shaped as viewed from above. Fig.2 illustrates the body has openings evenly spaced about the circumference. Schafer discloses the body has a continuous front arc and a continuous back arc with two radiuses of curvature either equal or different, col. 2, lines 26-32. Schafer also discloses the implant body can be made of a metal or polymer, col. 3, lines 14,15. According to Figs. 1 and 3, it can be construed that the width is greater than the length.

Apparently recognizing that the Schafer reference includes no teaching at all regarding the length-to-width ratio of 2.4 recited in claim 30, the Examiner provides this alternative obviousness position:

> Regarding Claim 30 is also rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Schafer et al. It would have been obvious to one of ordinary skill in the art to modify the ratio of length to width to have a width at least 2.4 times greater the length for Schafer's implant since such a modification only involves routine skill in the art and would be considered by surgeons as they treat patients of various sizes, for example children would have smaller dimensions as opposed to adults requiring a much larger cage.

Applicant fully addressed these rejections in the previous Amendment. Nevertheless, the Examiner provided the following Response to Arguments:

> Applicant's arguments filed 9/4/07 have been fully considered but they are not persuasive. Applicant argues that the spinal prosthesis disclosed by Schafer et al. is not banana-shaped, but kidney shaped. First the Examiner would like to point out that all bananas are not the same shape since there are numerous types of bananas that vary in size, shape and color. There are dwarf and red bananas that are short. Then there are Cavendish bananas that are longer and yellow. Then there is the plantain banana that is long and greenish with a more elongate appearance and less of curved look to them than the yellow Cavendish type. Thus, there is not an exact or specific shape that is implied, just because Applicant's claim recites "banana-

shaped". Applicant also alleges the Schafer device looks like a cage similar to a device invented by Harms which the Applicant says is kidney-shaped and not banana-shaped. Comparing the prior art with other prior art is irrelevant and thus the Examiner would like to illustrate a comparison of Applicant's device with that of Schafer's as shown below.

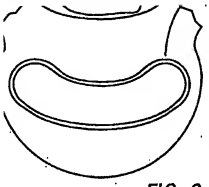


FIG. 6

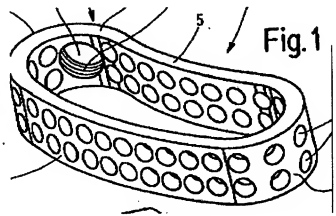


Fig.1

The figure on the left is the claimed invention and the figure on the right is the prior art device disclosed by Schafer. One of ordinary skill would clearly state they look identical. Applicant also argues the Examiner has not shown where the different radius of curvature is disclosed. However, it appears the Applicant's representative has totally ignored or overlooked that the Examiner referred to col. 2, lines 29-31 in the office action where two different radii are disclosed by Schafer. Applicant again compares the prior art device of Harms with the prior art Schafer implant in addressing the rejection of claim 30 made by the Examiner. The Examiner would like to note that a comparison of prior art not relied on is a moot point and the Examiner will not entertain these issues.

Applicant argues that the dimensions of Schafer's device cannot be modified as claimed. However, clearly one of ordinary skill in the art is capable of modifying an implant's size to accommodate the different anatomical dimensions found in patients.

Further, in response to Applicant's continuing arguments with respect to claims 1 ("banana-shaped") and 30 ("the banana-shape of the unitary body includes a width and length wherein the width is at least 2.4 times greater than the length") that it is ***the shape of the prosthesis that is critical to the invention***, and that ***the key dimensions in the dependent claims are the ratio of length to width that defines the banana-shape*** – the Examiner asserted in the Advisory Action that:

> the Examiner is not persuaded by Applicant's comments that size is irrelevant to bananas, when the claims are being disputed over a size limitation. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. It is noted Applicant referred to drawings to support what was meant by the term "banana-shaped". However, drawings are not read into claims. It is words that describe a drawing that define an invention. The Examiner has presented his position in the Final and the rejections are maintained.

B. Rejection under 35 U.S.C. 103 of Claims 10-12, 15-18, 20-27, 29, and 31

Of these claims, the only claim argued separately by Applicant herein is claim 25, which stands rejected over Schafer in view of Michelson (US 6,302,914). Specifically, the Examiner states (quoting only the full paragraphs that relate to claims that are argued herein):

> Claims 24, 25, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Michelson (6302914). Schafer et at. is explained above. However, Schafer et al. fail to disclose the implant's width or length. Michelson (Fig. 18) shows a spinal cage for supporting the vertebrae. Michelson also teaches that the height and width of the implant correspond to the area that a disc may heave been removed, col. 7, lines 47-56. It would have been obvious to one of ordinary skill in the art to use an implant with a width falling within the range of 24-28mm and a length of about 10mm as taught by Michelson for the implant of Schafer et al. such that it can provide the proper dimensions of the patients intervertebral space and support adjacent vertebrae.

VII. ARGUMENT

Schafer fails to disclose the beneficial banana-shaped prosthesis of claim 1. Accordingly, Applicant traverses the rejection of claim 1 below. Schafer, along with all of the other prior art, teaches that the prosthesis should be kidney-shaped and that the shape should match the shape of the vertebral body where it will be implanted. Applicant's banana-shape is expressly different from the shape of the vertebral body and different from the kidney-shape of Schafer.

In addition, Applicant asserts that claim 30, which depends from claim 1 and further defines the banana-shaped prosthesis as having a width to length ratio of at least 2.4, is not

anticipated by Schafer, and further is non-obvious over Schafer. As noted, Schafer teaches away from this shape that Applicant has discovered to be beneficial.

Finally, Applicants further assert that claim 25, which depends from claim 24 and ultimately from claim 1, and which recites a length of about 8 to 10 mm and a width of about 24 to 28 mm (and thus a width-to-length ratio that is at least 2.4), is further non-obvious over Schafer in combination with Michelson. Michelson teaches different dimension, and further, like Schafer, teaches away from Applicant's beneficial shape.

A. Claim 1 is not Anticipated by Schafer (US 6,143,032)

While Applicant very much appreciates the Examiner's humor, as well as his encyclopedic and downright mouth-watering knowledge of various bananas – both the rejection and the Response to Arguments miss the point: (1) banana-shaped and kidney-shaped are different; and (2) the Examiner has still not stated any valid reason to design a prosthesis having a width that is at least 2.4 times greater than the length – and in fact, the prior art uniformly teaches away from such a design.

1. The Meaning of "Banana-Shaped"

Applicant is entitled to employ terminology that most suitably describes his invention, and may employ drawings to facilitate clarity in its description. Item 15 of the figures plainly shows an embodiment of Applicant's claimed intervertebral prosthesis that is of a banana-shape. This shape is referred to throughout the specification as "banana-shaped." Applicant has characterized that embodiment in the claims as a "banana-shape." Moreover, Applicant has specifically contrasted his "banana-shaped" intervertebral prosthesis with prior art intervertebral prostheses and has described the advantages that come from shaping the prosthesis in the manner that the manner that the Applicant has shaped it.

Applicant does not and has never contended that "banana-shaped" in the claims means anything other than its ordinary meaning. Everyone, including the person of ordinary skill in the art, knows what the shape of a banana is. Webster's Third New International Dictionary (P. Gove, ed., Merriam-Webster 1986), a dictionary that has been cited by the Federal Circuit Court of Appeals in patent cases more than 100 times, defines "banana" as follows: "the ***elongated often curved and usu. tapering*** fruit of the banana plant having soft pulpy flesh and a rind that is usu. yellow or orange-colored when ripe and dark brown to black at full maturity" (emphasis

added) (p. 169). It should come as no surprise that the definition of banana begins with its shape, as bananas have a distinctive and well understood shape.

It goes without saying, as the Examiner notes, that bananas come in different sizes and colors – but size and color is irrelevant to the claim term "banana-shaped." Large bananas are banana-shaped just as small bananas are banana-shaped. Green bananas are banana-shaped just as yellow bananas are banana-shaped. It is also true that there is some variation in the shape of bananas, but this variation is quite limited, and in every case, the shape of the banana is distinct from the shape of a kidney – a point that the Examiner never addresses.

2. The Kidney-Shaped Prosthesis of Shafer Does Not Anticipate the Claimed Banana-Shaped Prosthesis

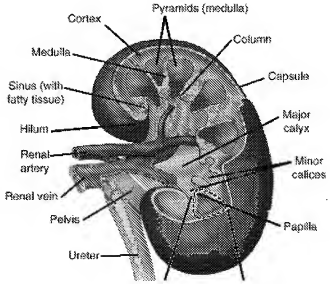
According to the Office Action, "Fig. 3 [of Schafer] shows a unitary body that is banana-shaped as viewed from above." Figure 3 does not show such a shape and Schafer expressly states otherwise. Rather than being banana-shaped, the device of Schafer, and particularly as disclosed in Figure 3, is kidney-shaped:

> In a preferred embodiment, the side wall of the hollow body is curved in a ***kidney-shaped*** fashion . . . so that the intervertebral implant can ***best match the shape of the vertebral bodies***. . . . FIGS. 1 and 3 ***clearly show that the intervertebral implant 1 is approximately kidney-shaped***. [Column 1, lines 25-45 and Column 2, lines 58-59.]

The shape of a kidney is also well known, including to those of ordinary skill in the art. Dorland's Illustrated Medical Dictionary defines "kidney" as follows (emphasis added):

> kidney (kid·ney) (kid´ne) [L. ren; Gr. nephros] either of the two organs in the lumbar region that filter the blood, excreting the end-products of body metabolism in the form of urine, and regulating the concentrations of hydrogen, sodium, potassium, phosphate, and other ions in the extracellular fluid. Called also ren [TA]. Each human kidney is ***about 11 cm long, 5-7.5 cm wide***, and 2.5 cm thick, and weighs from 120-160 gm. ***The kidney is of characteristic shape***, with a notch known as the hilum on its inner, concave border; renal vessels and nerves and the ureter pass through it, and it communicates with the cavity or sinus of the kidney. The kidney consists of a cortex (see renal cortex, under cortex) and a medulla (see renal medulla, under medulla). The medullary substance forms pyramids, whose bases are in the cortex and whose apices, the renal papillae, project into the calices of the kidney. The renal pyramids number from 10 to 15. The parenchyma of

each kidney is composed of about one million renal tubules (nephrons, the functional unit of the kidney), held together by a little connective tissue. Each tubule begins blindly in a renal corpuscle, consisting of a glomerulus and the surrounding glomerular capsule, situated within the cortex. After a neck or constriction below the capsule, it becomes the proximal convoluted tubule, then Henle's loop, then the distal convoluted tubule, the connecting tubule, and finally the straight collecting tubule, which opens at the apex of a renal papilla. The straight collecting tubules converge as they descend, forming groups in the center, known as medullary rays.



The kidney thus has a characteristic shape with a width to length ratio (as those dimensions are defined in the application) of 11/7.5 to 11/5 – or about 1.5 to 2.2. The characteristic shape of a kidney is thus not only qualitatively distinguished from the more elongate banana shape, but the ratio of width to length is quantitatively outside of the range specified in claim 30 of greater than 2.4.

Schafer expressly defines the shape of its prosthesis as "kidney shaped," and further states that it is kidney shaped for a reason – that is, it fits better to the vertebrae if it is kidney shaped. Indeed, there is a long history of kidney-shaped spinal prostheses that are designed to match the shape of the vertebral bodies they contact. Applicant's claimed prosthesis is different precisely because it is banana-shaped. In particular, the banana-shaped prosthesis of the claims is thinner than the fatter kidney-shape of the prior art. It is this difference in shape that provides

the benefits of the claimed invention (namely, that it can easily be inserted from key approaches) as quoted extensively from the specification above.

The Examiner strenuously responded to Applicant's reference to the Harms patent (US 4,820,305) that had previously been relied upon to reject the claims. In fact, the Harms reference is highly relevant. Harms expressly teaches that:

> Preferably the cross-section is chosen as a function of the cross-section of the parts to be connected. For connection of the vertebrae/body in the lumbal region the member preferably comprises a kidney-shaped cross-section. . . Column 3, lines 20-24.

Like Schafer, Harms shows a kidney-shaped prosthesis. The clearest way to visualize why the prior art (both Schafer and Harms) use a kidney-shaped prosthesis is to compare the banana-shaped prosthesis of Figure 6 of the present application (in reference to the vertebral body) to Figure 6 of Harms, which shows a kidney-shaped prosthesis.:

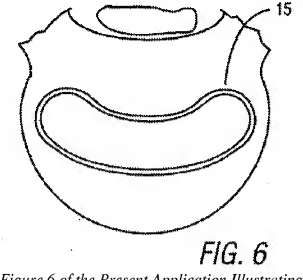


Figure 6 of the Present Application Illustrating Applicant's Banana-Shaped Prosthesis Set Against a Vertebral Body

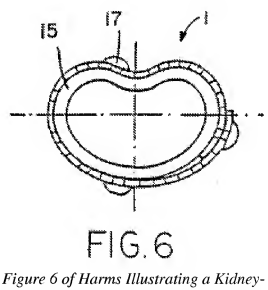


Figure 6 of Harms Illustrating a Kidney-Shape that is Better Matched to the Shape of the Vertebral Body

It is readily apparent that the kidney-shaped prosthesis (here illustrated from Harms) matches the shape of the prosthesis quite closely (which is why both Schafer and Harms prefer this shape, with Schafer saying multiple times as "kidney-shaped" and is said to be kidney-shaped in order to "best match the shape of the vertebral bodies"). Meanwhile, Applicant's

preferred "banana-shaped" prosthesis is elongate and curved – consistent with the definition of banana. The kidney shapes are much fatter and will fit within the intervertebral space in a very different way.

Finally, the Examiner provides a top view of Applicant's banana-shaped prosthesis, next an isometric view of Schafer's kidney-shaped prosthesis, and states that "[o]ne of ordinary skill would clearly state they look identical." One of ordinary skill would not attempt to determine if the shapes were the same by comparing different views. Looking at the top view of Schafer, Schafer is clearly fatter and less curved – that is, it is more kidney-shaped, as Schafer says it is.

There is no doubt that Schafer does not disclose a "banana-shaped" prosthesis – it discloses a "kidney-shaped" prosthesis that is different from "banana-shaped." Accordingly, Schafer cannot anticipate claim 1.

B. Shafer Fails to Anticipate or Render Obvious Claim 30

The Examiner rejects claim 30 as anticipated without ever providing support for the recitation of claim 30 that "the banana-shape of the unitary body includes a width and length wherein the width is at least 2.4 times greater than the length." There being no such disclosure in Schafer, claim 30 likewise cannot be anticipated by Schafer.

The Examiner apparently appreciates this lack of disclosure in Schafer and states that "[r]egarding Claim 30 [sic] is also rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Schafer et al." In order to make out an obviousness rejection, the Examiner must provide clear reasons why the person of ordinary skill would make the leap from the prior art (a kidney-shaped prosthesis) to the claims (a banana-shaped prosthesis wherein the banana-shape of the unitary body includes a width and length wherein the width is at least 2.4 times greater than the length). *See In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds ***cannot be sustained by mere conclusory statements***; instead, there ***must be some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness") (emphasis added). Without such rational underpinning, the Examiner easily fall prey to improper hindsight reasoning:

> A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. *See Graham*, 383 U.S., at 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard

> against slipping into the use of hindsight'".) *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (Apr. 30, 2007).

Here, the Examiner's rational underpinning for the obviousness of claim 30 is that:

> It would have been obvious to one of ordinary skill in the art to modify the ratio of length to width to have a width at least 2.4 times greater the length for Schafer's implant since such a modification only involves routine skill in the art and would be considered by surgeons as they treat patients of various sizes, for example children would have smaller dimensions as opposed to adults requiring a much larger cage.

Claim 30 have nothing to do with size and has no size limitations whatsoever. Claim 30 is about shape. The Examiner's basis for rejecting this claim as obvious is that:

> It would have been obvious to one of ordinary skill in the art to modify the ratio of length to width to have a width at least 2.4 times greater the length for Schafer's implant since such a modification only involves routine skill in the art and would be considered by surgeons as they treat patients of various sizes, for example children would have smaller dimensions as opposed to adults requiring a much larger cage.

But the key feature of the ***claimed shape makes the prosthesis different from the patient's physiology.*** If the Examiner's hypothetical surgeon were a person of ordinary skill in the art, that surgeon would pick a size and shape of prosthesis that matches the size and shape of the patient's vertebral body – because that is what all of the art of record (including Schafer) teaches. Claim 30 expressly teaches a different shape that does not match up with the patient's vertebral body because Applicant has discovered that the claimed shape has other over-riding benefits – and these benefits are clearly stated in the application. Namely, the presently claimed shape provides for safer and more convenient implantation from a variety of approaches in a single step. For example, the specification provides The shape of the claimed banana-shaped prosthesis makes the prosthesis "easier and safer to place within the prepared disc space," allows it to "be placed from an anterior position (anterior interbody fusion or ALIF), or posteriorly (posterior lumbar interbody fusion or PLIF, transforaminal interbody fusion or TLIF)," "in a single step implantation procedure," while being "mechanically more stable than the previous two component systems currently in use." All of these many advantages to Applicants' device derive directly from its shape – and, contrary to the Examiner's assertion, the ratio of width to length serves to structurally define this critical shape.

Applicant has developed a shape that provides these benefits despite the express teaching in the very prior art reference relied upon by the Examiner not to shape the prosthesis this way. The Examiner's *ex post facto* reasoning would frustrate the very purpose of the kidney shape in the prior art – ***Schafer teaches to make the prosthesis look like the vertebral body while the supposedly obvious modification would make the prosthesis look less like the vertebral body***. As one would expect, the law of obviousness does not permit this approach. According to MPEP § 2143.01(V), "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the propose modification" (citation omitted). Further, in accordance with MPEP § 2143.01(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious" (citation omitted). Here, the issue is shape, and the prior art teaches that the prosthesis should take the shape of the vertebral body. The modification would make the prosthesis look less like the vertebral body. There is no reasoning for doing to Schafer the opposite of what Schafer teaches.

C. Schafer and Michelson (US 6,301,914) Fail to Render Obvious Claim 25

Claim 25 depends from claim 24, which in turn depends from claim 13, which in turn depends from claim 1. Claim 25 recites that the "prosthesis has a length in a range of between about 8 mm and about 10 mm." By virtue of its dependence from claim 24, it also recites that the "prosthesis has a width in a range of between about 24 mm and about 28 mm." These dimensional recitations result in a width to length ratio of about 2.4 to 3.5 (24/10 to 28/8; similar to claim 30 which recites a width to length ratio of at least about 2.4).

1. Schafer Fails to Disclose the Banana-Shape and the Recited Dimensions

As described above, Schafer fails to disclose, teach or suggest a prosthesis having a width to length ratio of at least about 2.4 – and Schafer, in fact, teaches the opposite (*i.e.*, a fatter kidney-shaped prosthesis). Schafer thus fails to disclose, teach, or suggest the banana-shape. In addition, Schafer, as recognized by the Examiner, fails to disclose, teach, or suggest the recited dimension.

2. Michelson Fails to Fill In the Gaps Left By Schafer

The Examiner states that it would have been obvious "to use an implant with a width falling within the range of 24-28 mm and a length of about 10 mm ***[sic; 10 mm is the height in Michelson]***, as taught by Michelson for the implant of Schafer et al. such that it can provide the proper dimensions of the patients intervertebral space and support adjacent vertebrae."

Claim 25 recites width and length dimensions of Applicants' banana-shaped prosthesis, and the Michelson reference relied upon by the Examiner expressly describes different dimensions that result in a different shape from that recited by Applicants. Michelson expressly states that:

> The ***size of the implant 100 is substantially the same size as the disc material that it is replacing . . . .*** In the preferred embodiment in regard to the lumbar spine the implant 100 is approximately 28-48 mm wide, approximately 36 mm being preferred. . . . The depth would at its maximum range from 20 to 34 mm with 26 to 32 being the preferred maximum depth. [Column 7, lines 40-52.]

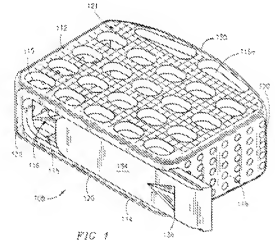


FIG 1

Michelson Prosthesis 100

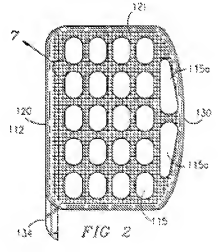


FIG 2

Top View of Michelson Prosthesis Showing it is Not Banana-Shaped

These dimensions are expressly different than those recited by Applicant as Michelson is meant to fit within the spine differently. Michelson wants his prosthesis to be substantially the same size as the disc that it is replacing – as is clear from Applicant's Figure 6 above, Applicant's prosthesis is smaller than the disc. Further, Applicant's banana-shaped prosthesis is much narrower. The length of Applicants' prosthesis (the smaller of the two dimensions) is

preferably about 8 to 10 mm, while Michelson's depth (the dimension that corresponds to Applicants' length) is said to be 20 to 34 mm – ***meaning that Michelson's prosthesis is two to more than three times fatter than Applicant's***. As is apparent from Figures 1 and 2 of Michelson above, Michelson's prosthesis is extraordinarily different in shape from the present claims and that difference can be seen directly in the enormously different dimensions.

As explained above with extensive quotes from the application, these large differences in dimension are not merely the result of picking and choosing an appropriate range based on the size of the patient – according to the present application:

> The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use. The curvature of the cage of the invention mirrors the natural curvature of the anterior and posterior curves of the vertebral bodies. It can be placed from either the anterior position or posterolateral position after standard discectomy. [Paragraph 50.]

The shape of Applicants' prosthesis, and its corresponding dimensions (a shape and dimensions that are not disclosed, taught or suggested in any of Schafer or Michelson, alone or combined), achieve these results, results that are different from and better than those obtained in the art. The Examiner has not found these features in the art, nor has the Examiner provided any credible rational under which a person of ordinary skill in the art would choose them. Accordingly, no *prima facie* obviousness rejection has been made out.

3. Schafer and Michelson Cannot Be Combined In the Manner Attempted by the Examiner as the Art of Record Teaches Against It

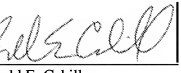
Schafer, as quoted above, teaches that the prosthesis should take the shape of the vertebral bodies it contacts. Michelson, as quoted above, teaches that the prosthesis should take the shape of the vertebral disc it replaces. Even Harms, previously cited by the Examiner but not presently relied upon and also quoted above, prefers the kidney shape as it better approximates the shape of the vertebral body of the lumbar spine. Accordance with MPEP § 2143.01(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious" (citation omitted). Here, the issue is shape,

and the prior art teaches that the prosthesis should take the shape of the vertebral body or disc. The combination/modification (as noted above, even the combination of Schafer and Michelson teaches the wrong dimensions) would make the prosthesis look less like the vertebral body. Case law forbids this combination.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,



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CLAIMS APPENDIX

1. (Previously Presented) An intervertebral prosthesis for implantation between adjacent vertebrae of the human spine, comprising:

a unitary body that is banana-shaped as viewed from above, the unitary body having an exterior surface and an interior surface, the interior surface defining an interior recess;

the unitary body defining openings that are evenly spaced about a circumference of the unitary body; and

wherein the banana shape of the unitary body includes a front arc that has a first radius of curvature and a back arc that includes a second radius of curvature.

2. (Canceled)

3. (Previously Presented) The intervertebral prosthesis of Claim 1 wherein the first radius of curvature is equal to or less than the second radius of curvature.

4. (Canceled)

5. (Original) The intervertebral prosthesis of Claim 3, wherein the first radius of curvature is less than the second radius of curvature.

6. (Original) The intervertebral prosthesis of Claim 5, wherein the first and the second radii of curvature extend from a single point of rotation.

7-9. (Canceled)

10. (Previously Presented) The intervertebral prosthesis of Claim 1, wherein the defined openings are quadrilaterals.

11. (Previously Presented) The intervertebral prosthesis of Claim 10, wherein the quadrilaterals are parallelograms.

12. (Previously Presented) The intervertebral prosthesis of Claim 11, wherein the parallelograms are rhombuses.

13. (Previously Presented) The intervertebral prosthesis of Claim 1, wherein the body of the intervertebral prosthesis includes at least one material selected from the group consisting of a metal, a carbon fiber, and a polymer.

14. (Previously Presented) The intervertebral prosthesis of Claim 13, wherein the body of the intervertebral prosthesis includes a metal.

15. (Original) The intervertebral prosthesis of Claim 14, wherein the metal includes at least one member selected from the group consisting of titanium and metal alloy.

16. (Original) The intervertebral prosthesis of Claim 15, wherein the metal includes a metal alloy.

17. (Original) The intervertebral prosthesis of Claim 16, wherein the metal alloy is a stainless steel.

18. (Previously Presented) The intervertebral prosthesis of Claim 13, wherein the body of the intervertebral prosthesis includes a carbon fiber.

19. (Previously Presented) The intervertebral prosthesis of Claim 13, wherein the body of the intervertebral prosthesis includes a polymer.

20. (Original) The intervertebral prosthesis of Claim 19, wherein the polymer is a bioreabsorbable polymer.

21. (Previously Presented) The intervertebral prosthesis of Claim 20, wherein the bioreabsorbable polymer includes at least one member selected from the group consisting of polyglycolic acid and polylactic acid.

22. (Previously Presented) The intervertebral prosthesis of Claim 19, wherein the polymer includes polymethylmethacrylate.

23. (Previously Presented) The intervertebral prosthesis of Claim 22, wherein the polymethylmethacrylate is blended with an antibiotic.

24. (Original) The intervertebral prosthesis of Claim 13, wherein the intervertebral prosthesis has a width in a range of between about 24 mm and about 28 mm.

25. (Original) The intervertebral prosthesis of Claim 24, wherein the intervertebral prosthesis has a length in a range of between about 8 mm and about 10 mm.

26. (Original) The intervertebral prosthesis of Claim 25, wherein the intervertebral prosthesis has a height in a range of between about 10 mm and about 16 mm.

27. (Original) The intervertebral prosthesis of Claim 26, wherein the front arc of the prosthesis has a thickness in a range of between about 1.5 mm and about 2 mm.

28. (Previously Presented) The intervertebral prosthesis of Claim 1, wherein the front arc and the back arc are continuous.

29. (Previously Presented) The intervertebral prosthesis of Claim 1, wherein the unitary body includes upper and lower edges that each form smoothly-sloping surfaces, said upper and lower edges including bands that form a serpentine arrangement of an interlinked mesh.

30. (Previously Presented) The intervertebral prosthesis of Claim 1, wherein the banana-shape of the unitary body includes a width and length wherein the width is at least 2.4 times greater than the length.

31. (Previously Presented) The intervertebral prosthesis of Claim 30, wherein the length is in a range of between about 8 mm and about 10 mm.

EVIDENCE APPENDIX

No evidence has been submitted.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

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